JUN 0 7 2013

SECTION 8
510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K131051.

807.92 (a)(1): Name: Hitachi Chemical Diagnostics
Address: 630 Clyde Court
Mountain View, CA 94043

Phone: (650) 961 5501
FAX: (650) 969 2745
Contact: Mr. Charles Tsou

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name:
S TEST Reagent Cartridge Total Protein (TP)
S TEST Reagent Cartridge Albumin (ALB)

Common Name: Routine chemistry analyzer for TP
Routine chemistry analyzer for ALB

Classifications: 21 CFR § 862.1635 Total Protein (TP)
21 CFR § 862.1035 Albumin (ALB)

807.92 (a)(3): Identification of the legally marketed predicate devices
Cobas c systems TP2 (Roche Diagnostics, Inc., Indianapolis, IN)- K100853
Cobas c systems ALB2 (Roche Diagnostics, Inc., Indianapolis, IN)- K100853

807.92 (a)(4): Device Description
The Hitachi Clinical Analyzer is an automatic, bench-top, wet chemistry system intended for use in clinical laboratories or physician office laboratories. The instrument consists of a desktop analyzer unit, an operations screen that prompts the user for operation input and displays data, a printer, and a unit cover. The analyzer unit includes a single probe, an incubation rotor, carousels for sample cups and reagent cartridges, and a multi-wavelength photometer. The single-use reagent cartridges may be placed in any configuration on the carousel, allowing the user to develop any test panel where the reagent cartridges are available.

The S TEST reagent cartridges are made of plastic and include two small reservoirs capable of holding two separate reagents (R1 and R2), separated by a reaction cell/photometric

cuvette. The cartridges also include a dot code label that contains all chemistry parameters, calibration factors, and other production-related information, e.g., expiration dating. The dimensions of the reagent cartridges are: 13.5 mm (W) × 28 mm (D) × 20.2 mm (H).

System operation: After the sample cup is placed into the carousel, the analyzer pipettes the sample, pipettes the reagent, and mixes (stirs) the sample and reagent together. After the sample and reagent react in the incubator bath, the analyzer measures the absorbance of the sample, and based on the absorbance of the reactions, it calculates the concentration of analyte in the sample. The test system can measure analytes in serum or plasma and results are available in approximately 15 minutes per test. This submission is for Reagent Cartridges TP and ALB.

Chemistry reactions: (TP) Proteins in samples react with the biuret reagent to form a purple-red complex. The concentration of total protein can be determined by measuring the absorbance of the purple-red substance.

(ALB) Albumin in the sample combines with bromcresol green to form a blue-green dye conjugate. The albumin concentration is directly proportional to the color intensity and can be determined photometrically by measuring the absorbance of this resulting blue-green color.

807.92 (a)(5): Intended Use

The S TEST Reagent Cartridge Total Protein (TP) is intended for the quantitative determination of TP in serum, lithium heparinized plasma, K3 EDTA plasma and sodium citrate plasma using the HITACHI Clinical Analyzer E40. The S TEST Reagent Cartridge TP is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Total protein measurements are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.

The S TEST Reagent Cartridge Albumin (ALB) is intended for the quantitative determination of ALB in serum, lithium heparinized plasma, K3 EDTA plasma and sodium citrate plasma using the HITACHI Clinical Analyzer E40. The S TEST Reagent Cartridge ALB is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

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807.92 (a)(6): Technological Similarities and Differences to the Predicate

The following chart describes similarities and differences between the TP test systems.

Characteristic	Hitachi S TEST Systems	PREDICATE
Instrument Platform	Hitachi Clinical Analyzer (originally cleared under K111753)	Roche cobas c systems – K100853
Total Protein (TP)	K number- 131051	Roche K number- K100853
Device Class, Regulation Code	Class II, Exempt, Reserved, 21 CFR 862.1635	Same, except Exempt (not POC)
Classification Product Code	JGQ	Same
Intended Use	Quantitative determination of TP	Same
Testing Environment	Physician office or clinical lab	Clinical lab
Test Principle	Proteins in samples react with the biuret reagent to form a purple-red complex. The concentration of total protein can be determined by measuring the absorbance of the purple-red substance.	Divalent copper reacts with protein peptide bonds to form the characteristic purple-colored biuret complex. The color intensity is directly proportional to the protein concentration which is determined photometrically
Specimen Type	Human serum or plasma	Same
Reportable Range	0.2 to 11.0 g/dL	0.2 to 12.0 g/dL
Detection Wavelength	546/700 nm	Same
Detection Limit	0.2 g/dL	Same
Linearity	0.2 to 11.0 g/dL	0.2 to 12.0 g/dL
Precision	%CVs range from 1.8% to 2.5%	%CVs range from 0.9% to 2.5%

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The following chart describes similarities and differences between the ALB test systems.

Characteristic	Hitachi S TEST Systems	PREDICATE
Instrument Platform	Hitachi Clinical Analyzer (originally cleared under K111753)	Roche cobas c systems – K100853
Albumin (ALB)	K number- K131051	Roche K number- K100853
Device Class, Regulation Code	Class II, 21 CFR 862.1035	Same
Classification Product Code	CIX	Same
Intended Use	Quantitative determination of ALB	Same
Testing Environment	Physician office or clinical lab	Clinical lab
Test Principle	Albumin in the sample combines with bromcresol green to form a blue-green dye conjugate. The albumin concentration is directly proportional to the color intensity and can be determined photometrically by measuring the absorbance of this resulting blue-green color.	Same
Specimen Type	Human serum or plasma	Human serum, plasma, or urine
Reportable Range	0.5 to 7.1 g/dL	0.2 to 6.0 g/dL
Detection Wavelength	660/700 nm	570/505 nm
Detection Limit	0.1 g/dL	0.2 g/dL
Linearity	0.1 to 8.0 g/dL	0.2 to 6.0 g/dL
Precision	%CVs range from 1.6% to 4.8%	%CVs range from 0.7% to 1.2%

807.92 (b)(1): Brief Description of Nonclinical Data

A series of studies were performed that evaluated the following nonclinical performance characteristics for each analyte: analytical sensitivity (limits of detection), linearity, 20-day in-house precision, interference testing, in-house method comparisons, and matrices comparison between serum and various plasma types.

Analytical Sensitivity (Limits of Detection)- TP

The study followed CLSI EP17-A, and the limit of detection was found to be 0.2 g/dL. The quantitation limit was found to be 0.2 g/dL

Analytical Sensitivity (Limits of Detection)- ALB

The study followed CLSI EP17-A, and the limit of detection was found to be 0.1 g/dL. The quantitation limit was found to be 0.5 g/dL.

Linearity- TP

The study followed CLSI EP-6A, and the range of linearity was 0.2 to 11.0 g/dL. The reportable range is 0.2 to 11.0 g/dL.

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Linearity- ALB
The study followed CLSI EP-6A, and the range of linearity was 0.1 to 8.0 g/dL. The reportable range is 0.5 to 8.0 g/dL.

20-day In-house Precision- TP
The studies followed CLSI EP5-A2, where three levels of samples were each tested in two runs, twice a day, for 20 days. The results were as follows:

Precision Summary:

TP- Low, Level 1, Summary

TP	Within-Run	Total
Mean (g/dL)	4.19	4.19
SD (g/dL)	0.05	0.09
%CV	1.1%	2.1%

TP- Middle, Level 2, Summary

TP	Within-Run	Total
Mean (g/dL)	5.51	5.51
SD (g/dL)	0.08	0.14
%CV	1.4%	2.5%

TP- High, Level 3, Summary

TP	Within-Run	Total
Mean (g/dL)	7.19	7.19
SD (g/dL)	0.07	0.13
%CV	1.0%	1.8%

20-day In-house Precision- ALB
The studies followed CLSI EP5-A2, where three levels of samples were each tested in two runs, twice a day, for 20 days. The results were as follows:

Precision Summary:

ALB- Low, Level 1, Summary

ALB	Within-Run	Total
Mean (g/dL)	2.28	2.28
SD (g/dL)	0.04	0.11
%CV	1.5%	4.8%

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ALB- Middle, Level 2, Summary

ALB	Within-Run	Total
Mean (g/dL)	4.72	4.72
SD (g/dL)	0.07	0.13
%CV	1.4%	2.8%

ALB- High, Level 3, Summary

ALB	Within-Run	Total
Mean (g/dL)	6.01	6.01
SD (g/dL)	0.07	0.09
%CV	1.2%	1.6%

Interference Testing (per CLSI EP7-A2)
The data demonstrated that the **TP** test system was not affected by high levels of the following substances at the levels noted:

Unconjugated bilirubin: no interference up to 50 mg/dL
Lipemia: no interference up to 500 mg/dL
Ascorbic acid: no interference up to 50 mg/dL
Hemoglobin: no interference up to 1,000 mg/dL

Lack of interference was defined as recoveries between 90% and 110% of the neat value, and assay performance claims were established on the HITACHI Clinical Analyzer by testing two serum pools containing approximately 4.0 and 6.5 g/dL TP.

The data demonstrated that the **ALB** test system was not affected by high levels of the following substances at the levels noted:

Hemoglobin: no interference up to 250 mg/dL
Unconjugated bilirubin: no interference up to 12.5 mg/dL
Lipemia: no interference up to 500 mg/dL
Ascorbic acid: no interference up to 50 mg/dL

Lack of interference was defined as recoveries between 90% and 110% of the neat value, and assay performance claims were established on the HITACHI Clinical Analyzer by testing two serum pools containing approximately 2.5 and 4.0 g/dL ALB

Method Comparison - **TP**
A total of 115 clinical specimens spanning the dynamic range (0.8 g/dL to 10.9 g/dL), were assayed in singleton and in a blinded fashion by both the Hitachi E40 system and a standard laboratory system. The comparative data were analyzed by Deming regression and are shown below. (CI = confidence interval)

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TP Regression Statistics:

n	r	Slope (95% CI)	y-intercept (95% CI)	X mean	Y mean
115	0.989	1.02 (1.01 to 1.04)	0.01 (-0.13 to 0.15)	7.0	7.2

Method Comparison - **ALB**

A total of 118 clinical specimens spanning the dynamic range (0.5 g/dL to 6.4 g/dL), were assayed in singleton and in a blinded fashion by both the Hitachi E40 system and a standard laboratory system. The comparative data were analyzed by Deming regression and are shown below. (CI = confidence interval)

ALB Regression Statistics:

n	r	Slope (95% CI)	y-intercept (95% CI)	X mean	Y mean
118	0.975	1.01 (0.96 to 1.06)	0.24 (0.06 to 0.41)	4.0 g/dL	4.3 g/dL

Matrices Comparisons- TP

A study was performed to validate the use of three plasma types as an alternative to serum for the Hitachi Clinical Analyzer with S TEST Reagent Cartridge TP. The plasma types were sodium citrate, K3 EDTA, and lithium heparin. Forty-five (45) matched serum/plasma samples that spanned the dynamic range (0.5 to 10.5 g/dL) were assayed in singleton and the results were compared using linear regression (plasma = y-axis, each type). The performance characteristics were as follows.

n = 45, range (serum) = 0.5 to 10.5 g/dL TP

	Heparinized Plasma	EDTA Plasma	Na Citrate Plasma
Slope (95% CIs)	1.00 (0.96 to 1.04)	1.00 (0.96 to 1.04)	0.98 (0.93 to 1.03)
y-intercept (95% CIs)	-0.11(-0.43 to -0.21)	-0.06 (-0.33 to 0.22)	-0.09 (-0.45 to 0.26)
r	0.989	0.992	0.987

Matrices Comparisons- ALB

A study was performed to validate the use of three plasma types as an alternative to serum for the Hitachi Clinical Analyzer with S TEST Reagent Cartridge ALB. The plasma types were sodium citrate, K3 EDTA, and lithium heparin. Forty-one (41) matched serum/plasma samples that spanned the dynamic range (1.0 to 7.1 g/dL) were assayed in singleton and the results were compared using linear regression (plasma = y-axis, each type). The performance characteristics were as follows.

N = 41, Range (serum) = 1.0 to 7.1 g/dL ALB

	Heparinized Plasma	EDTA Plasma	Na Citrate Plasma
Slope (95% CIs)	0.99 (0.95 to 1.03)	0.95 (0.92 to 0.98)	1.00 (0.94 to 1.05)
y-intercept (95% CIs)	-0.01 (-0.20 to 0.18)	0.22 (0.08 to 0.36)	-0.22 (-0.48 to -0.03)
r	0.992	0.995	0.986

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807.92 (b)(2): Brief Description of Clinical Data

Studies for precision and method comparison (accuracy) were performed at three external POL-type sites to evaluate the Hitachi E40 Clinical Analyzer with S TEST Reagent Cartridges TP and ALB in one of its targeted intended use environments, the physician's office laboratory.

For the external site precision study, each site received three blinded serum samples (the Precision Panel, labeled A, B, and C) that were chosen to represent low, middle, and high concentrations of TP or ALB. Each sample was assayed six times per day for five days, reporting 30 results per level. Precision estimates for total precision were as follows:

TP (g/dL)
n = 30 replicates per sample per site

Site #	Sample	Mean	Within-run Precision		Total Precision	
		(g/dL)	SD (g/dL)	%CV	SD (g/dL)	%CV
1	A	4.1	0.05	1.2%	0.07	1.6%
2	A	4.1	0.05	1.1%	0.07	1.6%
3	A	3.8	0.05	1.4%	0.13	3.5%
1	B	5.5	0.05	0.8%	0.06	1.1%
2	B	5.5	0.06	1.2%	0.07	1.2%
3	B	5.0	0.04	0.9%	0.20	4.0%
1	C	7.1	0.05	0.7%	0.05	0.7%
2	C	7.1	0.06	0.8%	0.07	0.9%
3	C	6.5	0.07	1.1%	0.28	4.4%

ALB (g/dL)
n = 30 replicates per sample per site

Site #	Sample	Mean	Within-run Precision		Total Precision	
		(g/dL)	SD (g/dL)	%CV	SD (g/dL)	%CV
1	A	0.88	0.03	3.9%	0.04	4.8%
2	A	0.80	0.00	0.0%	0.00	0.0%
3	A	0.81	0.02	2.8%	0.04	4.5%
1	B	4.67	0.05	1.0%	0.04	1.3%
2	B	4.60	0.05	1.6%	0.06	1.7%
3	B	4.47	0.12	2.7%	0.13	2.8%
1	C	7.03	0.05	0.8%	0.18	2.5%
2	C	6.93	0.06	0.8%	0.11	1.6%
3	C	6.72	0.08	1.2%	0.16	2.3%

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For the external method comparison studies, a series of approximately 50 - 80 serum specimens with TP values ranging from 0.6 to 10.9 g/dL, and ALB values ranging from 0.5 to 6.7 g/dL, were assayed on the Hitachi E40 Clinical Analyzer at three sites using S TEST Reagent Cartridges TP and ALB (y) and a comparative method as the reference method (x). Deming regression analyses yielded the following results:

POL ACCURACY DATA SUMMARY- TP (g/dL)

Site #	n	Range (g/dL)	Regression Equation	"r"	CI* Slope	CI Intercept
1	52	0.8 to 10.8	y = 0.98x + 0.14	0.996	0.96 to 1.01	0.00 to 0.29
2	52	0.8 to 10.9	y = 1.00x - 0.07	0.994	0.97 to 1.03	-0.31 to 0.16
3	53	0.6 to 10.5	y = 0.96x + 0.03	0.996	0.93 to 0.98	-0.14 to 0.19

*95% Confidence Interval

POL ACCURACY DATA SUMMARY- ALB (g/dL)

Site #	n	Range (g/dL)	Regression Equation	"r"	CI* Slope	CI Intercept
1	87	0.5 to 6.7	y = 0.99x + 0.24	0.982	0.92 to 1.06	-0.06 to 0.53
2	81	0.5 to 6.6	y = 0.95x + 0.30	0.979	0.88 to 0.1.02	0.00 to 0.61
3	81	0.9 to 6.1	y = 0.91x + 0.35	0.985	0.85 to 0.97	0.10 to 0.60

*95% Confidence Interval

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

Nonclinical and clinical testing was performed for the Hitachi E40 Clinical Analyzer with Reagent Cartridges TP and ALB. The test systems were shown to be safe and effective for their intended uses.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 7, 2013

Hitachi Chemical Diagnostics, Inc
C/O Erika Ammirati
575 Shirlynn Court
LOS ALTOS CA 94022

Re: K131051
Trade/Device Name: Hitachi S TEST Reagent Cartridge Total Protein (TP)
Hitachi S TEST Reagent Cartridge Albumin (ALB)
Regulation Number: 21 CFR 862.1035
Regulation Name: Albumin test system
Regulatory Class: II
Product Code: CIX, JGQ
Dated: April 12, 2013
Received: April 17, 2013

Dear Ms. Ammirati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131051

Device Name: S TEST Reagent Cartridge Total Protein (TP)
S TEST Reagent Cartridge Albumin (ALB)

Indications For Use:

The S TEST Reagent Cartridge Total Protein (TP) is intended for the quantitative determination of TP in serum, lithium heparinized plasma, K3 EDTA plasma and sodium citrate plasma using the HITACHI Clinical Analyzer E40. The S TEST Reagent Cartridge TP is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Total protein measurements are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.

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Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k131051